

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/716,981	LIPPS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment after Non-Final submitted 21 February 2007.
2. ☒ The allowed claim(s) is/are 1-4, 7, 11, 12 and 17-21.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Applicants' attorney, John Casperson, indicated that the changes and/or additions were acceptable to Applicants on 26 April 2007. Should this change, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. In claim 1, insert "and a carrier" after "comprising a peptide"
2. Cancel claims 5-6, 8-10 and 14-16.

### ***Withdrawal of Restriction Requirement***

The restriction between elected Groups I and non-elected Groups III-VI is hereby withdrawn. Group III is drawn to forming antibodies with the claimed peptides, Group VI is drawn to contacting NGF with an antibody in vitro. Applicant is advised that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: The claims limited to the short peptides are free of the art. The closest prior art to SEQ ID NO: 3 is represented by Inoue et al. (cited in the previous Office action mailed 15 November 2006), which encompasses SEQ ID NO: 3, but with a single substitution:

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## RESULT 1

NGNJXI

nerve growth factor - Indian cobra

C;Species: Naja naja naja (Indian cobra)

C;Date: 30-Nov-1980 #sequence\_revision 25-Apr-1997 #text\_change 09-Jul-2004

C;Accession: S13927; A01401

R;Inoue, S.; Oda, T.; Koyama, J.; Ikeda, K.; Hayashi, K.

FEBS Lett. 279, 38-40, 1991

A;Title: Amino acid sequences of nerve growth factors derived from cobra venoms.

A;Reference number: S13927; MUID:91138755; PMID:1995338

A;Accession: S13927

A;Molecule type: protein

A;Residues: 1-116

A;Cross-references: UNIPROT:P01140; UNIPARC:UPI0000173386

A;Experimental source: venom

A;Note: the source is designated as Naja naja and referred to as Indian cobra, so we have assigned it to the most probable subspecies

R;Hogue-Angeletti, R.A.; Frazier, W.A.; Jacobs, J.W.; Niall, H.D.; Bradshaw, R.A.

Biochemistry 15, 26-34, 1976

A;Title: Purification, characterization, and partial amino acid sequence of nerve growth factor from cobra venom.

A;Reference number: A01401; MUID:76114772; PMID:1247508

A;Accession: A01401

A;Molecule type: protein

A;Residues: 1-11, 'P', 13-14, 'B', 16, 'TBT'; 20-21, 'GV'; 23-27, 'N', 29-31, 'AS', 34, 'S'; 36-48, 'E', 50-55; 56, 'RBSB', 61, 'PZP', 65-66, 'K'; 68-69, 'BTZ', 73-74, 'B', 76-79, 'TSNS', 84-90, 'BZG', 94, 'SA', 97-102, 'Z', 104-113, 115-116

A;Cross-references: UNIPARC:UPI0000173387; UNIPARC:UPI0000173388; UNIPARC:UPI0000173389; UNIPARC:UPI000017338A; UNIPARC:UPI000017338B; UNIPARC:UPI000017338C; UNIPARC:UPI000017338D

A;Experimental source: venom

A;Note: the source is designated as Naja naja and referred to as Indian cobra, so we have assigned it to the most probable subspecies

C;Comment: Nerve growth factor is necessary for the development of embryonic sympathetic and sensory neurons. Its role in snake venom is unclear.

C;Complex: homodimer

C;Superfamily: nerve growth factor beta chain

C;Keywords: growth factor; homodimer; venom

F;14-78,56-106,66-108/Disulfide bonds: #status predicted

Query Match 86.4%; Score 51; DB 1; Length 116;

Best Local Similarity 90.0%; Pred. No. 0.036;

Matches 9; Conservative 0; Mismatches 1; Indels 0; Gaps

0;

Qy 1 NLGEHPVCDS 10

||||| |||||

Db 7 NLGEHSVCDS 16

Similarly, the closest prior art to claims 17-21 is represented by Oldenburg et al. (cited in the previous Office action mailed 15 November 2006) and Esswein et al., DE19508672-A1, however both of the peptides disclosed therein contain more than 25 amino acids:

RESULT 8

AAW14312

ID AAW14312 standard; peptide; 34 AA.

XX

AC AAW14312;

XX

DT 30-APR-1997 (first entry)

XX

DE Cyclic parathyroid hormone (1-34) peptide 5.

XX

KW cyclic parathyroid hormone fragment; calcium-regulating activity;

KW osteoporosis; inhibit proliferation; epidermal cell; psoriasis;

KW improved half life; calcium retention; bone.

XX

OS Synthetic.

XX

FH Key Location/Qualifiers

FT Modified-site 13

FT /note= "forms lactam bridge with Orn at position 17"

FT Modified-site 17

FT /label= Orn

FT /note= "forms lactam bridge with Glu at position 13"

XX

PN DE19508672-A1.

XX

PD 12-SEP-1996.

XX

PF 10-MAR-1995; 95DE-01008672.

XX

PR 10-MAR-1995; 95DE-01008672.

XX

PA (BOEF ) BOEHRINGER MANNHEIM GMBH.

XX

PI Esswein A, Hoffmann E, Honold K, Schaefer W, Dony C;

XX

DR WPI; 1996-413519/42.

XX

PT Cyclic parathyroid hormone fragments with lactam bridge - have good in

PT vivo half life and are useful for treating osteoporosis and preventing

PT epidermal cell proliferation.

XX

PS Claim 6; Page 12; 14pp; German.

XX

CC New cyclic parathyroid hormone fragments (CPTH) have the amino acid

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CC sequence of h, b, p, r or CPTH(1-34), opt. extended by up to 4 amino  
 CC acids (aa) at the C-terminus and opt. shortened by up to 3 amino acids at  
 CC the N-terminus, and are cyclised between positions 13 and 17. One of  
 CC these positions is occupied by L- or D- Orn or Lys, and the other by L-  
 CC or D- Glu or Asp. CPTH have calcium-regulating activity (esp. for  
 CC treating osteoporosis and inhibit proliferation of epidermal cells (for  
 CC treating psoriasis). The CPTH have an improved half life in vivo than  
 CC known PTH fragments, increased mitogenicity and DNA-synthesising  
 CC capacity, reduced catabolic, calcium-mobilising activity and increased  
 CC activity for calcium retention and incorporation into bone. AAW14308-16  
 CC are claimed CPTH of the invention  
 XX  
 SQ Sequence 34 AA;

Query Match 100.0%; Score 29; DB 2; Length 34;  
 Best Local Similarity 100.0%; Pred. No. 35;  
 Matches 5; Conservative 0; Mismatches 0; Indels 0; Gaps  
 0;

Qy 1 NLGEH 5  
 |||||  
 Db 10 NLGEH 14

Some patent applications disclose peptides similar to SEQ ID NO: 4 that contain  
 less than 25 amino acids, however, they have various substitutions. For example,  
 Schubert et al. (U.S. Patent No. 6,984,486) disclose a peptide similar to SEQ ID NO 4:

RESULT 48  
 US-09-913-927D-5  
 ; Sequence 5, Application US/09913927D  
 ; Patent No. 6984486  
 ; GENERAL INFORMATION:  
 ; APPLICANT: Ulrich Schubert  
 ; APPLICANT: Peter Henklein  
 ; APPLICANT: Victor Wray  
 ; TITLE OF INVENTION: SYNTHETIC PEPTIDE OF REGULATORY VIRUS  
 ; TITLE OF INVENTION: PROTEIN R (VPR) OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1  
 ; TITLE OF INVENTION: (HIV-1) AND THE UTILIZATION THEREOF  
 ; FILE REFERENCE: 151.2USW0  
 ; CURRENT APPLICATION NUMBER: US/09/913,927D  
 ; CURRENT FILING DATE: 2002-01-14  
 ; PRIOR APPLICATION NUMBER: PCT/DE00/00525  
 ; PRIOR FILING DATE: 2002-02-19  
 ; PRIOR APPLICATION NUMBER: DE 199 08 752.0  
 ; PRIOR FILING DATE: 1999-02-19  
 ; PRIOR APPLICATION NUMBER: DE 199 08 766.0  
 ; PRIOR FILING DATE: 1999-02-19  
 ; NUMBER OF SEQ ID NOS: 11  
 ; SOFTWARE: FastSEQ for Windows Version 4.0

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; SEQ ID NO 5
; LENGTH: 15
; TYPE: PRT
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Synthetic peptide of regulatory virus proteins R
; OTHER INFORMATION: (vpr) of human immunodeficiency virus type 1
; OTHER INFORMATION: (HIV-1)
US-09-913-927D-5
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Query Match          89.7%; Score 26; DB 2; Length 15;
Best Local Similarity 80.0%; Pred. No. 20;
Matches      4; Conservative 1; Mismatches 0; Indels 0; Gaps
0;
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Qy      1 NLGEH 5
        |||:|
Db      1 NLGQH 5
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In addition, the instant inventors disclosed the same peptides in copending application, U.S. Serial No. 10/242,175, however, the priority date does not pre-date the instant application.

In addition, claims 7, 11 and 12 are in vitro method claims, for which there are no enablement issues.

The amendment to claim 1 was made to clarify the invention. Claims 5, 6, 8-10, and 14-16 were canceled solely to facilitate allowance, without prejudice to Applicant's right to pursue the subject matter of these claims in a divisional application(s).


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

  
ELIZABETH KEMMERER  
PROJECT EXAMINER